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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,969

Applicant(s)

WALLACE ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of RCE dated 8-29-05, amendment and remarks dated 8-25-05 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 8-29-05 has been entered.

Claims 1 and 19-36 are pending in the instant application.

Double Patenting

1. Claims 1, 19-25, 28, 29 and 31-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,063,061. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims an extrudable biocompatible aqueous colloid (hydrogel), which is the same as that recite by the method claims of the patent. The hydrogel of the patented method also comprises a polysaccharide, gelatin or a clotting factor, as that claimed and further possesses the same characteristics i.e., swell, particle size and degradability, thus anticipating the instant claimed product.

Claim Rejections - 35 USC § 102

2. Claims 1, 19-24, 28, 29 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,110,484 to Sierra et al (Sierra).

Sierra discloses a biomedical implant comprising a matrix material and a biodegradable porosifying agent. Example 3 of Sierra (col. 7, lines 60 through col. 8, lines 1-20) disclose the preparation of cross-linked gelatin, in which gelatin is diluted with phosphate-buffered saline, cross-linked with SPEG, allowed to cool and form a gel. The resulting gel is lyophilized and pulverized (reads on instant fragmented) to particles of 20 to 150 microns. The resulting powdered gelatin is loaded into a syringe together with fibrinogen-Factor XII. Thus, the pulverized gelatin of Sierra meets the claim limitations fragmented, biocompatible, resorbable, single-phase aqueous colloid and the claimed particle size. With respect to the claim limitation "substantially free of free aqueous phase", the lyophilized and pulverized gelatin is essentially free of water. With respect to the degradation rate, the limitation is inherent to the pulverized gelatin because Sierra teaches the preparation of gelatin in the same procedure as in the instant examples. Therefore, the reference anticipates instant claims.

Claim Rejections - 35 USC § 103

3. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,110,484 to Sierra.

Sierra, discussed above, fails to specify the addition of an active agent together with the resorbable colloid as claimed. However, Sierra suggests adding

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a number of active agents such as growth factors, clotting factors, antimicrobial etc., to the biodegradable polymer matrix (col. 4, lines 49-67 and example 4).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add active agents such thrombin or other growth factors, antimicrobials etc., to the gelatin gel before loading the gel into the plunger of the syringe and delivering to the site of interest depending the required treatment in addition to wound healing or tissue remodeling because Sierra suggests matrix implants form dressings at the dressing or remodeling tissue site and yet enable release the desired therapeutic agents due to the fast in vivo degradation of the porosifying agents such as gelatin, calcium alginate etc.

The following rejections from the previous action have been maintained:

4. Claims 1, 20-23, 25, 30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,818,517 to Kwee et al (Kwee).

Kwee et al discloses a pharmaceutical preparation comprising a hydrogel polymer and a drug, which is introduced by means of an injection syringe, which reads on the instant applicator having an extrusion orifice. Kwee teaches that the composition provides water necessary for the preparation of the highly viscous hydrogel that is already part of the total composition (col. 1). Thus, the composition of Kwee does not contain any free aqueous phase other than the water that forms a part of the hydrogel. Kwee teaches that the polymer has a swelling capacity but does not state the claimed percentages. However, Kwee

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teaches dextrin as a suitable polymer (examples), which is a polysaccharide and thus the swelling capacity is inherent to dextrin of Kwee et al. Further, the claimed property of in vivo degradation time being less than one year is inherent to the polymer because Kwee teaches the same class of polymer i.e., a polysaccharide.

5. Claims 19, 24, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee).

Instant claims are directed to protein and non-biological hydrogel and particle size of the hydrogel. While Kwee does not explicitly teach the claimed features, Kwee teaches a hydrogel polymer and suggests polymers such as dextran, starch, polyvinyl alcohol, etc (col. 2) are capable of swelling in water and homogenously injected out of the syringe without causing any practical problems and release the drug slowly over a period of time. Further, Kwee teaches that the polymer is in the form of dry particles (claims) and also suggests that the hydrogel can be used in combination with any drug such as locally active drugs, bactericidal, anti-inflammatories, etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use a particulate natural or synthetic (non-biological) polymer such as polyvinyl alcohol, having an appropriate particle size, as a hydrogel in combination with the any desired drug because Kwee suggests that the dry particulate polymer which has a capability to swell is useful in releasing the drug over a long period of time

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without having the conventional drawbacks such as water being separated from the hydrogel during injection at the site of interest.

6. Claims 26-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwee et al (Kwee) in view of Berg et al.

Kwee fails to teach the claimed protein polymer, a clotting agent such as thrombin, or the claimed combination of polymers.

Berg teaches a collagen wound dressing material comprising resorbable collagen particles of 50 to 350 microns. Berg also teaches addition of several wound-healing agents such as growth factors, enzyme inhibitors, angiogenesis factors etc (col. 4). Berg teaches that collagen wound dressings are capable of swelling at the desired ratios and still be injectable (examples 5 and 10).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate collagen of Berg as a hydrogel in the teachings of Kwee and use the hydrogel alone or in combination with the hydrogels of Kwee for releasing drugs such as wound healing agents because Berg suggests that collagen dressings are capable of being resorbable, allow cellular in growth, and protect the wound to be treated while still permitting the required diffusion of gases and liquids.

Response to Arguments

Applicant's arguments filed 8-29-05 have been fully considered but they are not persuasive.

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Kwee:

Applicants argue that instant independent claims 1 and 35 have been amended to recite aqueous colloid, which is substantially free from a free aqueous phase and in contrast Kwee describes a two phase hydrogel that has a first phase including water-insoluble polymer and a second phase including a water-soluble thickening agent. It is argued that the thickening agent is added by Kwee to remedy the problem of not being able to syringe out the hydrogel completely. Applicants argue that the two-phase hydrogel fails to anticipate the instant single-phase aqueous colloid and for the same reason does not render the dependent claims obvious over Kwee alone or over Kwee in view of Berg.

Applicants' arguments are not found persuasive because, the disclosure of Kwee nowhere suggests that the hydrogel comprises two phases. Kwee teaches that the two-compartment syringe contains swellable polymer in one compartment and a thickening agent in either or both the compartments (lines bridging col. 1-2). Even assuming that the thickening agent is present in the second compartment, a mere separation of the polymer and the thickener (by Kwee) does not imply that the two components constitute two different phases. Applicants defines the term "hydrogel" (page 18, lines 7-11) as a composition "comprising" a single aqueous phase colloid and also describes the hydrogel as "comprises", thus allowing for the additional components such as thickening agents of Kwee to be present. Furthermore, Kwee clearly states that ultimately a hydrogel is introduced into the body cavity with the aid of an injection and that the hydrogel or suspension that is fully syringed out and with improved syringeability.

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Kwee fails to teach extrudable hydrogel as claimed because Kwee states hydrogel that contains gee water and is difficult to extrude through a syringe (t col. 1, lines 35-45). To address the problem, Kwee simply proposes adding a thickening agent to improve the syringe ability of the original hydrogel, which still contains free water (Kwee at col. 1, lines 45-48; emphasis added).

Kwee in view of Berg:

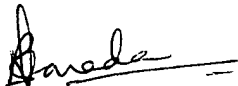
Applicants argue that Kwee fails to teach or suggest each and every element of independent claims and that Berg fails to remedy the deficiencies of Kwee. Applicants' arguments with respect to the rejection of Kwee in view of Berg have been considered but not found persuasive because as explained in the previous paragraphs, Kwee does teach the claimed product. The motivation to add the collagen hydrogels of Berg in the teachings of Kwee comes from the fact that both Kwee and Berg are directed to hydrogel polymers for therapeutic purposes and Berg suggests that collagen hydrogels are capable of swelling, injectable and are resorbable by the body. Therefore, the rejection has been maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 6.30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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November 10, 2005